

ASSEMBLY BILL

No. 2373

Introduced by Assembly Member Plescia

February 23, 2006

An act to amend Section 1261.6 of the Health and Safety Code, relating to health facilities.

LEGISLATIVE COUNSEL'S DIGEST

AB 2373, as introduced, Plescia. Automated drug delivery system.

Existing law provides for skilled nursing and intermediate care facilities that use an automated drug delivery system to store and distribute drugs to accurately track the movement of drugs into and out of the system.

This bill would include nursing facilities within the scope of that requirement.

Existing law provides that individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.

This bill would further limit that access to those persons described above when operating within their professional scope of practice.

Existing law requires that review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law, and specifies that the review include specified inspections and reviews.

This bill would extend the scope of the review to include a related discussion with facility staff using the system.

Existing law makes a violation of statutory requirements applicable to licensing of the above facilities a crime. By expanding the scope of the application of the above requirements to include nursing facilities that have an automated drug delivery system, this bill would change

the definition of a crime, thereby imposing a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 1261.6 of the Health and Safety Code is
2 amended to read:

3 1261.6. (a) (1) For purposes of this section and Section
4 1261.5, an “automated drug delivery system” means a
5 mechanical system that performs operations or activities, other
6 than compounding or administration, relative to the storage,
7 dispensing, or distribution of drugs. An automated drug delivery
8 system shall collect, control, and maintain all transaction
9 information to accurately track the movement of drugs into and
10 out of the system for security, accuracy, and accountability.

11 (2) For purposes of this section, “facility” means a health
12 facility licensed pursuant to subdivision (c), (d), or ~~both~~ (k), of
13 Section 1250 that has an automated drug delivery system
14 provided by a pharmacy.

15 (3) For purposes of this section, “pharmacy services” means
16 the provision of both routine and emergency drugs and
17 biologicals to meet the needs of the patient as prescribed by a
18 physician.

19 (b) Transaction information shall be made readily available in
20 a written format for review and inspection by individuals
21 authorized by law. These records shall be maintained in the
22 facility for a minimum of three years.

23 (c) Individualized and specific access to automated drug
24 delivery systems shall be limited to facility and contract
25 personnel authorized by law to administer drugs *and operating*
26 *within the scope of their professional scope of practice.*

1 (d) (1) The facility and the pharmacy shall develop and
2 implement written policies and procedures to ensure safety,
3 accuracy, accountability, security, patient confidentiality, and
4 maintenance of the quality, potency, and purity of stored drugs.
5 Policies and procedures shall define access to the automated drug
6 delivery system and limits to access to equipment and drugs.

7 (2) All policies and procedures shall be maintained at the
8 pharmacy operating the automated drug delivery system and the
9 location where the automated drug delivery system is being used.

10 (e) When used as an emergency pharmaceutical supplies
11 container, drugs removed from the automated drug delivery
12 system shall be limited to the following:

13 (1) A new drug order given by a prescriber for a patient of the
14 facility for administration prior to the next scheduled delivery
15 from the pharmacy, or 72 hours, whichever is less. The drugs
16 shall be retrieved only upon authorization by a pharmacist and
17 after the pharmacist has reviewed the prescriber's order and the
18 patient's profile for potential contraindications and adverse drug
19 reactions.

20 (2) Drugs that a prescriber has ordered for a patient on an
21 as-needed basis, if the utilization and retrieval of those drugs are
22 subject to ongoing review by a pharmacist.

23 (3) Drugs designed by the patient care policy committee or
24 pharmaceutical service committee of the facility as emergency
25 drugs or acute onset drugs. These drugs may be retrieved from an
26 automated drug delivery system pursuant to the order of a
27 prescriber for emergency or immediate administration to a
28 patient of the facility. Within 48 hours after retrieval under this
29 paragraph, the case shall be reviewed by a pharmacist.

30 (f) When used to provide pharmacy services pursuant to
31 Section 4119.1 of the Business and Professions Code, the
32 automated drug delivery system shall be subject to all of the
33 following requirements:

34 (1) Drugs removed from the automated drug delivery system
35 for administration to a patient shall be in properly labeled units of
36 administration containers or packages.

37 (2) A pharmacist shall review and approve all orders prior to a
38 drug being removed from the automated drug delivery system for
39 administration to a patient. The pharmacist shall review the

1 prescriber's order and the patient's profile for potential
2 contraindications and adverse drug reactions.

3 (3) The pharmacy providing services to the facility pursuant to
4 Section 4119.1 of the Business and Professions Code shall
5 control access to the drugs stored in the automated drug delivery
6 system.

7 (4) Access to the automated drug delivery system shall be
8 controlled and tracked using an identification or password system
9 or biosensor.

10 (5) The automated drug delivery system shall make a complete
11 and accurate record of all transactions ~~which~~ *that* will include all
12 users accessing the system and all drugs added to, or removed
13 from, the system.

14 (6) After the pharmacist reviews the prescriber's order, access
15 by licensed personnel to the automated drug delivery system
16 shall be limited only to the drug as ordered by the prescriber and
17 reviewed by the pharmacist and that is specific to the patient.
18 When the prescriber's order requires a dosage variation of the
19 same drug, licensed personnel shall only have access to the drug
20 ordered for that scheduled time of administration.

21 (g) The stocking of an automated drug delivery system shall
22 be performed by a pharmacist. If the automated drug delivery
23 system utilizes removable pockets or drawers, or similar
24 technology, the stocking system may be done outside of the
25 facility and be delivered to the facility if all of the following
26 conditions are met:

27 (1) The task of placing drugs into the removable pockets or
28 drawers is performed by a pharmacist or by an intern pharmacist
29 or a pharmacy technician working under the direct supervision of
30 a pharmacist.

31 (2) The removable pockets or drawers are transported between
32 the pharmacy and the facility in a secure tamper-evident
33 container.

34 (3) The facility, in conjunction with the pharmacy, has
35 developed policies and procedures to ensure that the pockets or
36 drawers are properly placed into the automated drug delivery
37 system.

38 (h) Review of the drugs contained within, and the operation
39 and maintenance of, the automated drug delivery system shall be
40 done in accordance with law and shall be the responsibility of the

1 pharmacy. The review shall be conducted on a monthly basis by
2 a pharmacist and shall include a physical inspection of the drugs
3 in the automated drug delivery system, an inspection of the
4 automated drug delivery system machine for cleanliness, ~~and a~~
5 review of all transaction records in order to verify the security
6 and accountability of the system, *and a related discussion with*
7 *facility staff using the system.*

8 (i) Drugs dispensed from an automated drug delivery system
9 that meets the requirements of this section shall not be subject to
10 the labeling requirements of Section 4076 of the Business and
11 Professions Code or Section 111480 of this code if the drugs to
12 be placed into the automated drug delivery system are in unit
13 dose packaging or unit of use and if the information required by
14 Section 4076 of the Business and Professions Code and Section
15 111480 of this code is readily available at the time of drug
16 administration.

17 SEC. 2. No reimbursement is required by this act pursuant to
18 Section 6 of Article XIII B of the California Constitution because
19 the only costs that may be incurred by a local agency or school
20 district will be incurred because this act creates a new crime or
21 infraction, eliminates a crime or infraction, or changes the
22 penalty for a crime or infraction, within the meaning of Section
23 17556 of the Government Code, or changes the definition of a
24 crime within the meaning of Section 6 of Article XIII B of the
25 California Constitution.